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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00N–0598]

Food Labeling; Dietary Supplement Health Claims; Public Meeting Concerning Implementation of Pearson Court Decision and Whether Claims of Effects on Existing Diseases May Be Made as Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments on two topics pertaining to health claims in dietary supplement labeling. The first topic concerns implementation of the recent court of appeals decision in *Pearson* v. *Shalala* (*Pearson*). In *Pearson*, the U.S. Court of Appeals for the D.C. Circuit held that FDA's decision not to authorize four health claims for dietary supplements violated the First Amendment because the agency did not consider whether the claims, which failed to meet the ''significant scientific agreement'' standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims, could be rendered nonmisleading by adding qualifying language. The second topic on which we are requesting comments is whether claims about an effect on an existing disease may be made as health claims, or whether such claims should subject the product to regulation as a drug. We are holding this meeting to give the public an opportunity to provide information and views on these topics.

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DATES: The meeting will be held on April 4, 2000, from 10 a.m. to 6 p.m. Please register by close of business, March 28, 2000. Late registrations will be accepted contingent on space availability. Submit written comments by April 19, 2000.

ADDRESSES: The meeting will be held at Department of Education, Barnard Auditorium (Federal Building 6), 400 Maryland Ave., SW., Washington, DC. Building entrances are located on the Maryland Ave., SW. and C Street, SW. between 4th and 6th Streets, SW. Federal Building 6 is one block east of the L'Enfant METRO Subway Station's Maryland Ave. exit.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or via the FDA Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm.

FOR FURTHER INFORMATION CONTACT:

To register for the public meeting contact: Carole A. Williams, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4421, FAX 301–827–3052, e-mail pubmtg@oc.fda.gov.

For general information: Jeanne Latham, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4697, FAX 202–205–4594, e-mail JLatham@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published a number of regulations to implement the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act). We set forth general requirements for health claims in the labeling of conventional foods (58 FR 2478, January 6, 1993); authorized the use of seven health claims (58 FR 2665, 58 FR 2787, 58 FR 2820, 58 FR 2739, 58 FR 2537, 58 FR 2552, and 58 FR 2622); and denied the

use of five other claims (58 FR 2537 [dietary fiber and cancer], 58 FR 2552 [dietary fiber and coronary heart disease], 58 FR 2622 [antioxidant vitamins and cancer], 58 FR 2661 [zinc and immune function in the elderly], and 58 FR 2682 [omega-3 fatty acids and coronary heart disease]). We also initially denied one claim (58 FR 2606 [folic acid and neural tube defects]) that was later authorized (59 FR 433, January 4, 1994) and then modified (61 FR 8750, March 5, 1996). In response to the 1990 amendments and the Dietary Supplement Act of 1992, we issued regulations applying the general requirements for health claims for conventional foods to dietary supplements (59 FR 395, January 4, 1994). The general health claims regulations for both conventional foods and dietary supplements are in 21 CFR 101.14 and 101.70. The regulations on individual health claims are in 21 CFR 101.71 through 101.82.

Our general health claim regulations for dietary supplements and our decision not to authorize health claims for four specific substance/disease relationships were challenged in *Pearson* v. *Shalala* (*Pearson*). These four substance/disease relationships include: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 milligram of folic acid in dietary supplement form is more effective in reducing the risk of neural tube defect than a lower amount in conventional food form.

In 1998, the district court ruled for FDA in all respects (14 F. Supp. 2d 10 (D.D.C. 1998)). In January 1999, however, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)). The appeals court held that, based on the administrative record compiled in the challenged rulemakings, the First Amendment does not permit FDA to reject health claims that we determine to be potentially misleading unless we also reasonably determine that no disclaimer would eliminate the potential deception. As a result of the decision, we must reconsider our approach to authorizing health claims for dietary supplements. The court further held that the Administrative Procedure Act (the APA) requires FDA to clarify the ''significant scientific agreement'' standard for authorizing health claims, either by issuing a regulatory definition of significant scientific agreement or by defining it on a case-by-case basis.

On March 1, 1999, the Government filed a petition for rehearing *en banc* (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)). We announced in the **Federal Register** of December 22, 1999 (64 FR 71794), the availability of a guidance clarifying the significant scientific agreement standard. The guidance is available on the Internet at http:// vm.cfsan.fda.gov/dms/ssaguide.html.

In the **Federal Register** of December 1, 1999 (64 FR 67289), we published a notice informing the public of the steps we plan to follow to carry out the *Pearson* decision. This notice announced plans to hold a public meeting before initiating rulemaking to consider what changes to the general health claims regulations for dietary supplements may be warranted in light of *Pearson* (64 FR 67289 at 67290). We believe that our reevaluation of these regulations will benefit from a public meeting and an open discussion of all possible approaches to implementing the court's decision.

Also in December 1999, we declined to issue a proposed rule for a health claim relating dietary supplements containing saw palmetto extracts and symptoms associated with benign prostatic hyperplasia (BPH). The petition requesting authorization for the claim was denied by operation of law on December 1, 1999, and we issued a letter explaining our decision on the same day. Our basis for not proposing a rule was that we were unable to resolve, within the timeframe required, the novel policy issue, which the petition entailed. This issue is whether a health claim may include claims about mitigation or treatment of disease. To date, the health claims that we have authorized have been for reducing the risk of a disease. While this issue was not considered in *Pearson*, as a topic that also relates to the regulation of health claims, it is being included for discussion in this public meeting.

On December 7, 1999, the agency was sued by the petitioners who had requested FDA to authorize a health claim for saw palmetto extract and BPH (*Whitaker* v. *Shalala*, No. 1:99CV0247 (D.D.C. December 7, 1999)). The plaintiffs alleged that our denial of the petition violated the First Amendment to the Constitution, the 1990 amendments, and the APA. The plaintiffs asked

the court to order the agency to evaluate their petition under the health claims regulations. The case is stayed through May 26, 2000, while we consider whether claims of effects on an existing disease may be made as health claims rather than drug claims.

II. Scope of Discussion

We are holding the public meeting on April 4, 2000, in part to identify and discuss possible changes, in light of the *Pearson* decision, to our general health claim regulations as they apply to dietary supplements. Unlike the statutory provision for the use of health claims on dietary supplements (section 403(r)(5)(D) of the act (21 U.S.C. 343(r)(s)(D))), section 403(r)(3)(B)(i) of the act provides that FDA may authorize health claims on conventional foods only when there is significant scientific agreement among qualified experts that the totality of publicly available scientific evidence supports the claim. As a result of this statutory requirement for conventional foods and because the *Pearson* case involved only dietary supplements, this portion of the public meeting will be restricted to health claims on dietary supplements.

A second topic open for discussion is whether claims about mitigation or treatment of diseases and their symptoms may be appropriately made as health claims.

We anticipate that both discussions will include presentations from people whom we invite to participate as well as from members of the public.

A. Implementation of the Pearson Court Decision

We are requesting comment on how to implement the element of the *Pearson* decision addressing the use of qualified health claims on dietary supplements when the evidence supporting the claim does not meet the ''significant scientific agreement'' standard. In general, we request public comment on whether qualified health claim statements for dietary supplements can be made that would not mislead consumers, and, if so, what types of disclaimers or other qualifying language would be appropriate. We would specifically request that persons commenting in person and in writing consider and provide input on the questions listed below. Comments recommending a

particular regulatory approach should explain how that approach is consistent with the constitutional and statutory requirements to which FDA is subject.

1. What is the best regulatory approach for protecting and promoting the public health? Specifically, what approach to regulating health claims will: (a) Protect consumers from fraudulent and misleading claims; and (b) provide reliable, understandable information that will allow consumers to evaluate claims intelligently and identify products that will in fact reduce the incidence of diseases? By what criteria should implementation options be judged?

2. Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence? If so, what are the characteristics of effective qualifying language? How should the agency determine what constitutes an appropriately qualified claim? If the available information is not sufficient to answer these questions, what research needs to be done, and who should be responsible for doing it? The agency encourages those commenting to submit empirical data on the effectiveness of qualifying language.

3. Is there a way to preserve the existing regulatory framework for health claims consistent with the First Amendment?

4. If health claims are permitted based on a standard less rigorous than significant scientific agreement, what is the best way to distinguish among claims supported by different levels of evidence so that consumers are not misled? Does the word ''may'' in existing health claims accurately communicate the strength of the evidence supporting claims that meet the significant scientific agreement standard, or should other language be used?

5. If health claims are permitted based on a less rigorous standard, what actions can be taken to provide incentives to manufacturers to conduct further research on emerging substance-disease relationships?

6. The *Pearson* opinion mentions circumstances in which FDA might be justified in banning certain health claims outright (e.g., where the evidence in support of the claim is outweighed by

evidence against the claim, or where the evidence supporting it is qualitatively weaker than the evidence against it) (*Pearson*, 164 F.3d at 659 and n.10).

a. How should FDA determine when evidence supporting a health claim is outweighed by evidence against the claim?

b. How should FDA determine when evidence supporting a health claim is qualitatively weaker than the evidence against the claim?

c. Are there other circumstances in which health claims are inevitably misleading and cannot be made nondeceptive by qualifying language?

7. What safety information is necessary to prevent a health claim from being misleading? For example, such information might include side effects, drug and food interactions, and segments of the population who should not use the product or should consult a physician before doing so. When a product may have adverse effects unrelated to the subject of a scientifically valid health claim, is the claim misleading? Under what circumstances, if any, should the product be allowed to bear the claim?

8. What actions should the agency take to ensure that consumers receive all relevant information about the safety of products that bear health claims and about research on product safety?

B. Whether Claims of Effects on Existing Diseases May Be Made as Health Claims

All health claims that we have authorized since passage of the 1990 amendments have been claims about reducing the risk of a disease. However, the saw palmetto extract health claim petition (Docket Number 99P–3030) requests authorization to make a claim about effects on an existing disease. Thus, the petition proposes a significant expansion of the scope of health claims beyond those that are currently authorized.

The issue of whether health claims may be about effects on an existing disease arose in the context of a petition for a dietary supplement health claim. For this reason and because the other issue to be discussed at the public meeting concerns health claims for dietary supplements, the

focus of discussion will be the use of claims on labels or labeling of dietary supplements about effects on an existing disease. However, we recognize that this issue is likely to arise in the context of health claims for conventional foods as well. Any decision we make on this issue with respect to dietary supplements, therefore, will also affect the use of such claims for conventional foods.

The health claims provisions of the act were enacted as part of a statutory scheme that already included extensive regulatory requirements for drugs. Before the 1990 amendments, the drug provisions had been applied to foods, including dietary supplements, that made claims about effects on disease. Arguably, if Congress had intended to permit any kind of disease claim for foods, it could have exempted all foods bearing authorized health claims from the drug definition in section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)), which provides that an article ''intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease'' is a drug. Instead, Congress provided that a product that bears an authorized health claim shall not be classified as a drug solely because of the presence of the claim (21 U.S.C. 321(g)(1)(B)). Congress' decision to proceed in this manner, rather than by creating an unconditional exemption, suggests that it may have wanted the drug provisions to continue to apply to foods in certain circumstances. Similarly when the Dietary Supplement Health and Education Act (DSHEA) was enacted in 1994, Congress did not provide that dietary supplements are deemed to be foods in all circumstances; rather, it provided that dietary supplements are deemed to be foods ''except for purposes of section 201(g)'' of the act, the drug definition.

In interpreting the health claim provisions of the act and their relationship to the drug provisions of the act, FDA has tried to strike a balance between recognizing that foods, including dietary supplements, can influence disease outcomes without ceasing to be foods, and honoring the statutory distinction between drugs and foods. To that end, we included in our health claims regulations the requirement that a product that bears a health claim must establish that it is a food by demonstrating nutritive value (21 CFR 101.14(b)(3)). Moreover, in the preambles to the regulations, we distinguished between nutritional effects of food substances, which we said would

be an appropriate subject for a health claim, and effects that are therapeutic, medicinal, or pharmacological, which would not. (See, e.g., 56 FR 60537 at 60545 to 60546, November 27, 1991; 58 FR 2478 at 2501, January 6, 1993; and 59 FR 395 at 408, January 4, 1994.) FDA also emphasized that the relationship of a food or a food component to a disease is different from that of a drug because of genetic, environmental, and behavioral factors that affect the development of chronic diseases in addition to diet, and because of the complexity of foods themselves (58 FR 2478 at 2501). Therefore, we explained, some claims that would be appropriate as drug claims under section 201(g)(1)(B) would not be appropriate as health claims for foods because they ''imply a degree of association between the substance and the disease that is not supportable for any food'' (56 FR 60537 at 60552).

Further, we commented that it would be necessary for a health claim petitioner to ''show that the claimed effect on disease is associated with the normal functioning of the human body'' and that claims to ''correct an abnormal physiological function caused by a disease or health-related condition'' would be drug claims rather than health claims (59 FR 395 at 407 to 408). With respect to claims about effects on symptoms of a disease, we said:

[T]here is no provision in the act for the agency to exempt statements about symptoms of disease from causing products to be regulated as drugs. Although such statements may not be claims that the product will treat the disease that causes the symptoms, the statements clearly pertain to the mitigation of disease by addressing the symptoms caused by the disease. Section 201(g)(1)(B) of the act provides, in part, that articles intended for use in the mitigation of disease are drugs.

(59 FR 395 at 413)

Another relevant part of the statutory scheme is the medical foods definition, enacted as part of the Orphan Drug Amendments of 1988. The statutory definition of a medical food is ''a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by

medical evaluation'' (21 U.S.C. 360ee(b)(3)). Thus, medical foods are a category of foods intended for dietary management of disease through a nutritional mechanism.

By their very nature, claims about effects on an existing disease are aimed at people who are ill. To date, authorized health claims have been aimed either at the general population or at a population subgroup whose members are at risk for a particular disease but are not yet sick. Since there are already two categories of ingested products that bear claims targeted to people suffering from a disease, drugs and medical foods, the agency believes there is reason to question whether Congress also intended health claims to encompass such claims.

FDA is open to reexamining its past statements on this issue in light of subsequent developments, such as advances in science and technology, changes in the marketplace, and the passage of DSHEA. In considering the scope of the health claims provisions of the act, we will seek an interpretation that is consistent with the statutory provisions governing drugs and medical foods and that gives effect to each part of the statute.

We are inviting public comment on this issue, and in particular we are seeking input on the following questions. Comments recommending a particular regulatory approach should explain how that approach is consistent with the legal requirements to which FDA is subject.

1. Does the language and structure of the act restrict the permissible types of substance-disease relationships that can be described in a health claim? How should FDA interpret the health claim and drug provisions of the act and the medical food provision of the Orphan Drug Amendments in relationship to each other?

2. If FDA were to permit at least some claims about effects on an existing disease as health claims, what criteria should be used to determine when a claim is a permissible health claim and when it is a drug claim under section 201(g)(1)(B) of the act?

3. If FDA were to permit at least some disease treatment or mitigation claims as health claims, what about claims that are covered by an existing over-the-counter (OTC) drug monograph? For example, if there is an existing drug monograph on the use of a dietary ingredient in an OTC

drug product to treat or mitigate disease, and the monograph concludes that the substance is not safe and effective for the intended use, should FDA still consider authorizing a health claim for the substance-disease relationship?

III. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, we request that you register in writing with the contact person by March 28, 2000, by providing your name, title, business affiliation, address, telephone and fax number. To expedite processing, this registration information also may be sent to the contact person by fax to 301–827–3052, or sent by e-mail to pubmtg@oc.fda.gov. If you need special accommodations due to disability, please inform the contact person when you register. A permanent assistive listening device (ALD) is installed in Barnard Auditorium. The ALD can be used with either a hearing aid T-coil or a headset/receiver available at the auditorium. If, in addition to attending, you wish to make an oral presentation during the meeting, you must so inform the contact person when you register and submit: (1) A brief written statement of the general nature of the views you wish to present; (2) the names and addresses of all persons who will participate in the presentation; and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, we may have to limit the time allotted for each presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

IV. Comments

You may submit, on or before April 19, 2000, written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to FDADockets@oc.fda.gov or via the FDA Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. You should annotate and organize your comments to identify the specific issues to which they refer. Please address your comment to the docket number given at the beginning of this notice. You must submit two copies of comments,

identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

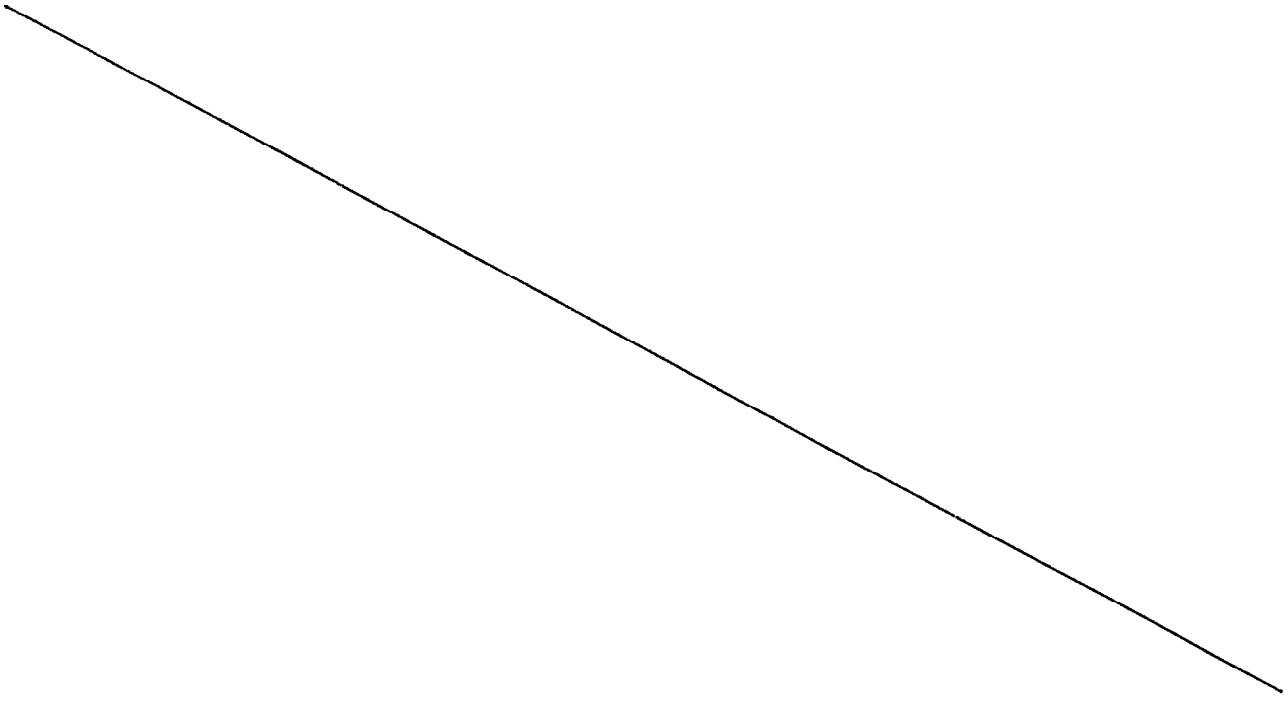
V. Transcripts

You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after April 14, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Internet at http://www.fda.gov.

VI. Reference

We have placed the following reference on display in the Dockets Management Branch. You may see it at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. *Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999).



REGISTRATION FORM

Public Meeting on Implementation of *Pearson* Court Decision and Expansion of Health Claims to Cover Claims of Effects on Existing Diseases

Instructions: To register, complete this form and mail or fax it to 301–827–3052 by March 28, 2000.

Name _____

Title _____

Company _____

Address _____

Telephone _____

Fax _____

E-mail _____

Please indicate the type or organization that you represent:

Industry ____

Government____

Consumer Organization____

Media____

Healthcare Professional____

Law Firm____

Educational Organization____

Other (specify)____

Do you wish to make an oral presentation?

Yes____

No____

If yes, you also must submit the following:

1. A brief statement of the general nature of the views you wish to present,

2. the names and addressed of all persons who will participate in the presentation, and

3. an indication of the approximate time that you request to make your presentation.

Dated: 3/10/00

March 10, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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